DETAILED ACTION

Status of the Claims

Claim(s) 1, 5, 7, 8, 10-13, and 15-70 are pending. Claim(s) 1, 5, 7, 8, 10-13, 19-22, and 60-70 are under examination. The following Office Action is in response to Applicant's communication dated April 2, 2010. The Office Action is NON-FINAL due to the new grounds of rejection presented below.

Claim Objections - Withdrawn

Applicant's claim amendments are sufficient to overcome the objection of claim(s) 11-13, 19-22, and 60 presented in the Office Action dated October 7, 2010.

Claim Rejections - 35 USC § 112 - Indefiniteness - Withdrawn

Applicant's claim amendments and are sufficient to overcome the rejection of claim(s) 8, 19-22, and 60 presented in the Office Action dated October 7, 2010. Thus, the rejection has been withdrawn.

Claim Rejections - 35 USC § 102 - Withdrawn

Applicant's claim amendments are sufficient to overcome the rejection of claim(s) 8 over Brennan. Thus, the rejection has been withdrawn.

Upon further consideration of the grounds of rejection of claims 5, 8, 10, 61, and 62 over Fodor, the rejection is withdrawn in view of the new grounds of rejection under 35 USC 103(a) presented below.

Claim Rejections - 35 USC § 102 - Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 remains rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (U.S. 5,474,796).

As an initial matter, it is submitted that the use of the term "A" to begin the claimed invention widens the breadth of the claimed nucleic acid fragment to encompass any nucleic acid fragment such as a dinucleotide sequence for example.

With specific regard to the terms "purified" and "isolated," such terms are not defined in the claim or specification to preclude the claimed oligonucleotide from existing within a prior art product. In other words, the claimed oligonucleotides are read in open or "comprising" language.

Brennan teaches the production of a solid support comprising immobilized extendable oligonucleotides that represent every possible permutation of the 10-mer

oligonucleotide (col. 9, example 4, for example). Thus, the product of Brennan inherently contains oligonucleotides that possess 100% identity or homology to 10-mer segments of SEQ ID NO: 1 and 4 as well as oligonucleotides that are perfectly complementary to 10-mer segments of SEQ ID NO: 1 and 4. Any fragment obtained by any method of specific amplification necessarily comprises a 10-mer that was present in the product according to Brennan. For example, the 20-mer recited in SEQ ID NO: 13 necessarily comprises a 10-mer that was present in the product according to Brennan. Thus, Brennan anticipates the claimed invention.

Response to Arguments

Applicant's arguments (see remarks pg. 21-22) have been fully considered but they are not persuasive.

First, the claimed invention does not require that the nucleic acid fragment necessarily include the sequence of both recited primers. Applicant is reminded that the claimed invention does not even require a specific type of amplification method or template sequence. Furthermore, even assuming the fragment is recited to require that both recited primers be part of the claimed nucleic acid fragment, such fragment remains recited in a manner that encompass any nucleic acid fragment such as a dinucleotide sequence for example. As recited above, any fragment obtained by any method of specific amplification necessarily comprises a 10-mer that was present in the product according to Brennan.

An amendment reciting "The purified or isolated nucleic acid fragment..." would obviate the instant rejection. However, Applicant is encouraged to amend the claim to explicitly require a specific type of amplification as well as inclusion of both primer sequences to obviate further rejection based on unintended claim breadth. Similar reasoning applies to claims 11-13.

Thus, the rejection is maintained.

Claim Rejections - 35 USC § 102 - New Grounds

The following rejection(s) are made in view of previously unconsidered prior art.

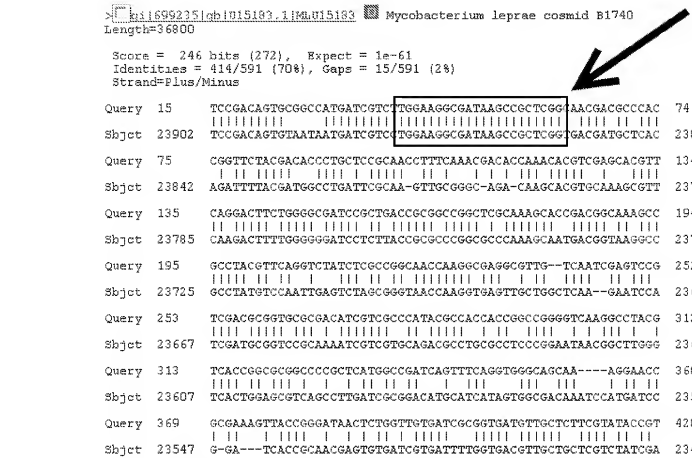
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 19, 69, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by NCBI (GENBANK Accession No. U15183; 9 March 1995).

NCBI teaches a purified and isolated nucleic acid fragment sequence comprising 22 consecutive nucleotides of SEQ ID NO: 4 (see figure below). With specific regard to the "wherein" clause, the phrase "susceptible to be used as a probe" is not defined by the claim or specification to preclude the application of NCBI as prior art because if the sequence of NCBI was contained within a composition with a 22-mer sequence of the

highlighted sequence under appropriate hybridization conditions, it would be a matter of simple point of view or semantics as to which sequence was in fact "probing" the other. Thus, NCBI anticipates the claimed oligonucleotide.



Claim Rejections - 35 USC § 103 - New Grounds

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim(s) 5, 8, 10-13, and 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al. (U.S. 2001/0053519 A1).

As an initial matter, as recited above, the claimed invention does not require that the nucleic acid fragment necessarily include the sequence of both recited primers. Furthermore, the claimed invention does not require a specific type of amplification method nor template sequence. Furthermore, even assuming the fragment is recited to require that both recited primers be part of the claimed nucleic acid fragment, such

fragment remains recited in a manner that encompass any nucleic acid fragment such as a 20-mer sequence for example.

Fodor teaches an "n-mer" array comprising every permutation of a 10-mer oligonucleotide (example 2, for example). The reference further suggests the production of solid supports comprising a set of every permutation (4^n) of different length oligonucleotides or n-mers in a range from 2-25-mers ([0100]-[0104]). For example, a 20-mer "n-mer array" product would have comprised every possible oligonucleotide of 20 bases in length. Thus, a product comprising a purified or isolated oligonucleotide of 20 contiguous nucleotides of SEQ ID NO: 4 (claims 8 and 11-13), or SEQ ID NOs 13-18 (claims 5, 10, and 61-64) would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention.

2. Claim(s) 5, 8, 11-13, 64, 69, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santos et al. (J Med Microbiol. 1993 Oct;39(4):298-304) in view of NCBI (GENBANK Accession No. U15183; 9 March 1995).

As an initial matter, as recited above, the claimed invention does not require that the nucleic acid fragment necessarily include the sequence of both recited primers. Furthermore, the claimed invention does not require a specific type of amplification method nor template sequence. Furthermore, even assuming the fragment is recited to require that both recited primers be part of the claimed nucleic acid fragment, such

fragment remains recited in a manner that encompass any nucleic acid fragment such as a 22-mer sequence for example.

Santos teaches designing a probe sequence to the *Mycobacterium leprae* genome (pg. 299, Southern hybridization, probe ML-97 5'- TTTTAGTGTG CATGTCATGG-3', for example). Santos does not specifically teach a sequence recited in claims 5, 8, or 11.

However, it is first noted that the *M. leprae* genome sequence, the sequence from which the Santos oligonucleotide was derived, is a sequence that was well known at the time of invention (see GENBANK Accession Nos. U15183). Thus, the binding site of a claimed oligonucleotide, a 22-mer for example, is suggested within the sequence disclosed by U15183 (see NCBI figure above).

Applicant is directed to *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

Furthermore, the recent court decision *KSR International Co. v. Teleflex Inc., 82* 127 SCt 1727 (2007), the U.S. Supreme Court determined that if the combination of the claimed elements was "obvious to try" by a person of ordinary skill, this might show that

such a combination was obvious under 35 USC §103. Regarding "obvious to try", the Court stated:

"A person of ordinary skill is also a person of ordinary creativity, not an automaton. The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

Thus, since the claimed sequences simply represent structural homologs of those sequences disclosed in the prior art, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds, the claimed 22-mer sequence within NCBI U15183 is *prima facie* obvious over the cited references in the absence of secondary considerations.

3. Claim(s) 21 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over NCBI (GENBANK Accession No. U15183; 9 March 1995) in view of Laqueyrerie et al. (U.S. 6,221,353 B1).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach recombinant cells.

Laqueyrerie teaches the production of recombinant cells comprising cosmids for the study of such cosmids (col. 17, lines 50-65, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to incorporate the NCBI cosmid into an E. coli cell for example since Laqueyrerie suggests such a product to produce copies of target cosmid sequences for further study.

Allowable Subject Matter

Claims 1 and 7 are allowed.

Claims 20, 22, and 65-68 are free of the prior art. Such claims are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1 and 7 are allowed.

Claims 5, 8, 10-13, 19-22, 60-64, 69, and 70 are rejected.

Claims 20, 22, and 65-68 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-

880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Primary Examiner
Art Unit 1637
Technology Center 1600